



Technical Specification

ISO/TS 24932

Genomics informatics — Procedures for gene expression panel-based similarity calculation for human pluripotent stem cell- derived organoids

*Informatique génomique — Procédures de calcul de similarité
fondées sur des panels d'expression génique pour les organoïdes
dérivés de cellules souches pluripotentes humaines*

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Procedures for gene data processing	3
4.1 Configuring data set from publicly available gene data source	3
4.2 Avoiding false-positive results	3
4.3 Configuring an organ specific gene expression panel	3
4.4 Construction of the algorithm method	5
4.5 RNA-seq production method	6
4.5.1 RNA-seq result generation	6
4.5.2 Minimum quality requirements for RNA-Seq data generation	6
4.5.3 Information management	6
4.6 RNA-seq result conversion method	6
Annex A (informative) Quantitative stomach similarity calculation for stomach organoid	8
Bibliography	12

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, Subcommittee SC 1, *Genomics and Multi-Omics Informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

An organoid is a self-organized three-dimensional tissue that is typically derived from stem cells, and which recapitulates the key functional and physiological complexity of an organ. Organoids mimic the cellular heterogeneity, functionality, architecture and molecular queue of the organ or diseased tissue from which they are derived.

Until now, to verify the similarity of organoids, the expression of organ-specific proteins or the activity of enzymes was tested to qualitatively evaluate the function of specific organs. However, it was difficult to quantitatively evaluate the similarity of various organoids produced in each laboratory because the criteria were different. The Korea Research Institute of Bioscience and Biotechnology (KRIBB) developed a quantitative prediction system to assess the similarity (percentage) of human pluripotent stem cell (hPSC)-derived organoids to the target organ, to improve conventional qualitative similarity assessment.

This document provides requirements and recommendations for developing a transcriptome-based quantitative calculation method for a simple and reproducible analysis of hPSC-derived human organoids similarity, and incorporates organ-specific characteristics to assess the differentiation level of hPSC-derived human organoids, enabling a simple and reproducible analysis of their similarity. In this context, the proposed method focuses on calculating organ-specific similarity (%) between hPSC-derived organoids and their corresponding target organs. This similarity serves as a quantitative indicator of organoid quality, where a higher similarity reflects a higher degree of maturation and functional fidelity to the target organ.

The quantitative calculation systems to assess organ-specific similarity based on Organ-specific Gene Expression Panels (Organ-GEP) utilize the Genotype Tissue Expression (GTEx) public database^[5] and Organ-GEP-based calculation algorithms, including a lung-specific gene expression panel (LuGEP), a stomach-specific gene expression panel (StGEP), and a heart-specific gene expression panel (HtGEP). GTEx is a large-scale database that analyses gene expression across multiple organs from healthy individuals of various age groups, sex and ethnicities. It is used to understand the functional characteristics, developmental processes, and disease mechanisms of each organ. Using this document, it is possible to create specific panels for various human organs, which can be used to calculate the quantitative organ-specific similarity for each hPSC-derived organoid. A specific example has been provided in [Annex A](#).

Based on the guidance and requirements of this document, a web-based similarity analytics system^[6] could be established to provide an analytical algorithm to calculate similarity (percentage) and gene expression patterns for direct comparison with cells differentiated into specific lineages using human target organ gene panels (e.g. liver, lung, stomach, heart), providing researchers with valuable information for generating high-similarity organoids ([Figure 1](#)).

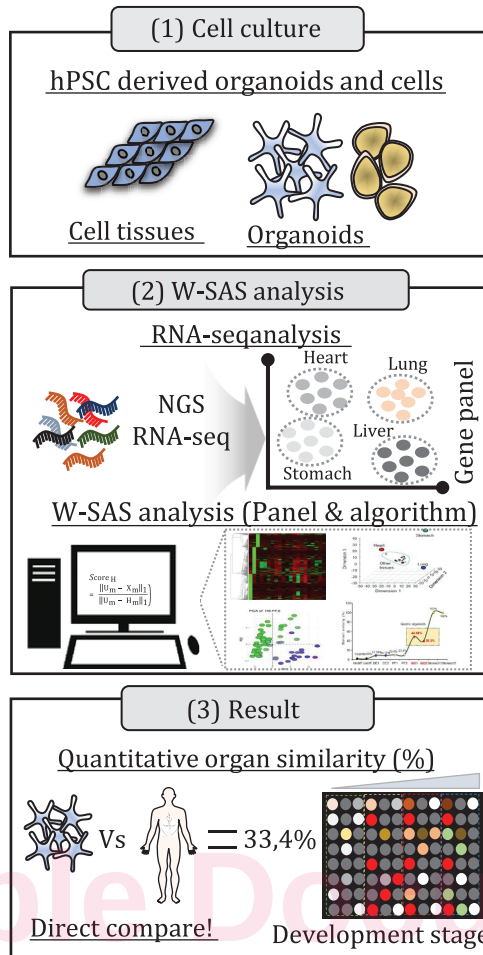


Figure 1 — Schematic overview of a similarity calculation system

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1 Scope

This document specifies procedures for gene expression-based similarity calculation between human pluripotent stem cell (hPSC)-derived organoids and a pre-defined data set of gene expression profiles in normal tissues. This document covers situations where the gene expression in the organoids have been quantified in a way functionally similar to the samples in the pre-defined dataset, and it is not intended for medical decisions.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1 algorithm

set of rules or calculations applied to test data that generate an interpretable or reportable result

[SOURCE: ISO 21474-1:2020, 3.2]

3.2 gene

specific sequence of nucleotides located on a chromosome as a functional unit of inheritance transferred from a parent to offspring

[SOURCE: ISO/TS 22690:2021, 3.7]

3.3 gene expression

process by which information from a *gene* (3.2) is used in the synthesis of a functional gene product

[SOURCE: ISO/TS 22690:2021, 3.9]

3.4 induced pluripotent stem cell iPSC

pluripotent stem cell (3.7) that is generated from somatic cells through artificial reprogramming by the introduction of *genes* (3.2) or proteins, or via chemical or drug treatment

[SOURCE: ISO 24603:2022, 3.17]